JAN 0 9 2003 K022622

BERKELEY ADVANCED BIOMATERIALS, INC.
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ISO9001 - ISO13485

510(K) Summary

In accordance with the Food and Drug Admisnistration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the Cem-Ostetic™ Bone Void Filler.

Submitted By:	Berkeley Advanced Biomaterials, Inc.
Date:	5 January 2003
Contact Person:	François Génin, Ph.D.
Position:	President and CEO
Contact Information:	Phone: 510-883-1644; Fax: 510-883-1315
Proprietary Name:	Cem-Ostetic™
Common Name:	Bone Void Filler
Classification Name and Reference:	Unclassified
Device Product Code and Panel Code:	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USES/INDICATIONS

Cem-Ostetic™ is an osteoconductive putty that is intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.

The putty may be shaped and pressed into the void by hand or inserted into a syringe and injected into the surgical site. The Cem-Ostetic™ paste set *in situ* or *ex situ* provides a void filler that can augment hardware to support bone fragments during the surgical procedure. The set putty acts as a temporary support medium and is not intended to provide structural support during the healing process. The implant is radio-opaque. Cem-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs.

B. DEVICE DESCRIPTION

Cem-Ostetic™ consists of a pre-measured formulation of distilled water and calcium-based compounds in a container that can be used to prepare a putty. Cem-Ostetic™ forms a paste when mixed with sterile distilled water. When 4 centimeter cubes (cc) of water are mixed with 10 cc of powder, the paste becomes hard after 5 minutes. Both powder and water are supplied pre-measured in separate containers. To prepare the putty, the water is first poured into the jar containing the powder and mixed with it for 60 seconds. For the next two minutes, the putty can be shaped into an implant or inserted into a syringe and injected into the surgical site (i.e., bony voids or gaps of skeletal system). The putty will harden on average within 5 minutes of contact between powder and water. The Cem-Ostetic™ powder and the water are supplied sterile for single patient use only.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

Cem-Ostetic™ is substantially equivalent to legally marketed, predicate devices OsteoSet BVF Kit and Osteoplast. The products have identical indications-for-use and identical contraindications. They also have the same warnings, precautions and potential adverse events. The technical characteristics of Cem-Ostetic™ are very similar to that of the predicate devices. The safety and effectiveness of Cem-Ostetic™ are adequately supported by the substantial equivalence information, materials data, and test results provided in the full document submitted within the scope of this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 9 2003

François Génin, Ph.D.
President and CEO
Berkeley Advanced Biomaterials, Inc.
1933 Davis Street Suite 307
San Leandro, California 94577

Re: K022622
Trade/Device Name: Cem-Ostetic™
Regulatory Class: Unclassified
Product Code: MQV
Dated: November 22, 2002
Received: December 3, 2002

Dear Dr. Génin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4660. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K022622**

Device Name: **Cem-Ostetic™ bone void filler**

Indications for Use:

Cem-Ostetic™ is an osteoconductive putty that is intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.
The putty may be shaped and pressed into the void by hand or inserted into a syringe and injected into the surgical site. The Cem-Ostetic™ paste set *in situ* or *ex situ* provides a void filler that can augment hardware to support bone fragments during the surgical procedure. The set putty acts as a temporary support medium and is not intended to provide structural support during the healing process. The implant is radio-opaque. Cem-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022622